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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/031,311	05/06/2002	Karin Briner	X-12591	5929	
25885 75	590 05/19/2003				
ELI LILLY AND COMPANY			EXAMINER		
PATENT DIVI P.O. BOX 6288			CHANG, CELIA C		
	1S, IN 46206-6288				
,			ART UNIT	PAPER NUMBER	
			1625	7	
			DATE MAILED: 05/19/2003		

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.    10/031,311   BRINER ET AL.	<del></del>	Application No.	Applicant(a)				
Examiner Cella Chang  - The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Repty  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ② MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. THE MAILING DATE OF THIS COMMUNICATION. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered to reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered the communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply specified above is less than thirty (30) days, a reply within the statutor in the mailing date of this communication. If the period for reply specified above, the meanimum statutory period will apply end will expose \$X\$ (if NORTHS from the mailing date of this communication. If the period for reply specified above, the meanimum statutory period will apply end will expose \$X\$ (if NORTHS from the mailing date of this communication.  Prior the specification is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under \$Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claim(s)  10 [Claim(s) 1-19 is/are replected.  10 [Claim(s) 1-19 is/are replected.  11 [Claim(s) 1-19 is/are rejected to yield the specification is objected to by the Examiner.  Application Papers  9 [The specification is objected to by the Examiner.  10 [The drawing(s) filed on 1 is/are: a) [accepted or b) [biplected to by the Examiner.  11 [The proposed drawing correction filed on 1 is/are: a) [accepted or b) [disapproved by the Examiner.  12 [The oath or dec			,				
Cella Chang  - The MAILING DATE of this communication appears on the cover sheet with the correspondence address — Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  1 Brown of time may be waitable under the provisions of 3 CFR 1.136(a). In no event, however, may a reply be timely filed after Six (b) MONTHS from the mailing date of this communication.  1 the period for reply specified above is less than thirty (20) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  1 th (N) period for reply specified above is less than thirty (20) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  1 the Operiod for reply specified above is less than thirty (20) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  1 the Operiod for reply specified above is less than three mailing date of this communication, seven if timely filed after Six (b) MONTHS from the mailing date of this communication, even if timely filed, may reduce almy seamed patient terms adjustment. See 37 CFR 1.704(b).  Status  1) Responsive to communication(s) filed on 03 September 2002  2a) This action is FINAL.  2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claim(s) 1.19 is/are pending in the application.  4a) Of the above claim(s) is/are allowed.  5) Claim(s) 1.19 is/are allowed.  6) Claim(s) 1.19 is/are allowed.  7) Claim(s) 1.19 is/are objected to by the Examiner.  Application Papers  9) The specification is objected to by the Examiner.  Application Papers  9) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  If approved, corrected drawings are required in reply to this Office action.  12) The cath or declaration is objected	Office Action Summary						
Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  I Statistics of time truly be available under the previous of 3 CFR 1.13(a). In no event, however, may a reply be timely filed distort or reply specified above, itses than thit; (93) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  If NO period for reply specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  If NO period for reply specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  Failure to negly within the set or extended period for reply will, by statute, cause the explication to become ABALONDE(S) (52, §133).  Any neply received by the Office later than these months after the mailing date of this communication, even if timely filed, may reduce any sessing period them adjustment. See 37 CFR 1.74(b).  Status  Status  Status  Status  A) Responsive to communication(s) filed on 0.3 September 2002.  2a) This action is FINAL. 2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 1-19 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) Claim(s) 1-19 is/are allowed.  6) Claim(s) 1-19 is/are rejected.  7) Claim(s) is/are allowed.  6) Claim(s) 1-19 is/are subject to restriction and/or election requirement.  Application Papers  9) The specification is objected to by the Examiner.  Application Papers  9) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  If approved, corrected drawings are required in reply to this Office action.  12) The proposed drawing correction filed on is/are: a) approved by	· · · · · · · · · · · · · · · · · · ·						
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THE MAILING DATE OF THIS COMMUNICATION.  Extensions of time may be available under the provisions of 37 CFR 1.35(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  If the period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  If the period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  Feature to reply within the set or extended period for reply by the propriet of reply within the set period will apply and will expire SIX (6) MONTHS from the mailing date of this communication, even if timely filed, may reduce any examed path the mailing date of this communication, even if timely filed, may reduce any examed path term adjustment. See 37 CFR 1.70(b).  Status  1) Responsive to communication(s) filed on 0.3 September 2002.  2a) This action is FINAL.  2b) This action is non-final.  3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims  4) Claim(s) 1-19 is/are pending in the application.  4a) Of the above claim(s) is a sylare withdrawn from consideration.  5) Claim(s) 1-19 is/are rejected.  7) Claim(s) 1-19 is/are rejected to .  8) Claim(s) 1-19 is/are rejected to .  8) Claim(s) 1-19 is/are rejected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Application Papers  9) The specification is objected to by the Examiner.  11) The proposed drawing correction filed on is/are: a) approved by disapproved by the Examiner.  12 if approved, corrected drawings are required in reply to this Office action.  12 The oath or declaration is objected to by the Examiner.  Priority under 35 U.S.C. §§ 119 and 120  13) Acknowledgment is made of a							
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	1. Certified copies of the priority documents	s have been received.					
3. Copies of the certified copies of the priority documents have been received in this National Stage		• •					
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) ☐ The translation of the foreign language provisional application has been received.  15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 5) Other:	2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) Notice of Informal F					

Application/Control Number: 10/031,311

Art Unit: 1625

## **DETAILED ACTION**

1. This application is a 371 of PCT/US00/17864.

A preliminary amendment has been filed and claims 7-19 were added. Claims 1-19 are pending.

2. Applicant is reminded of the proper content of an Abstract of the Disclosure.

The abstract being attached to the specification is the abstract of the WO 01/09126. this abstract contained unnecessary information for printing. It is recommended that complete revision of the content of the abstract on a separate sheet less than 250 words including structural formula. In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use.

3. Claims 1-19 recited the limitation "benzofuran nucleus" in claims 1-5. There is insufficient antecedent basis for this limitation in the claim.

It is noted that there is no benzofuran in the specification or in the formula of the claims. Clarification is required.

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hertel et al. US 6,353,008 or Hertel et al. US 6,436,964 or Hauser et al. US 6,465,453.

## Determination of the scope and content of the prior art (MPEP §2141.01)

Hertel et al. '008, '964 or Hauser et al. '453 disclosed structurally very close compounds of the claims, see '008 col. 10 formula (8) and col. 28 lines 55-64; '964 col. 9 formula (8) and col. 40 lines 31-39, '453 col. 7 formula (7a), col. 36, lines 55-64.

## Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Hertel '008, '964 or Hauser '453 disclosed all the elements of the claims **except** the species being exemplified are unsubstituted while the instant claims are drawn to methyl substituted compounds of the examples recited supra i.e. R<sup>5</sup>, R<sup>5</sup>, R<sup>6</sup>, R<sup>6</sup>, R<sup>7</sup>, R<sup>7</sup> are not all H.

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One having ordinary skill in the art would be in possession of the claimed compounds as taught generically by Hertel et al. '008, '964 or Hauser '453 given the explicit formula delineated and guided by the enabled species as recited supra **because** the final products of one methyl substituted or gem dimethyl substituted compounds have been exemplified (see '964 col. 89-90). One skilled in the art is in possession of the claimed compounds since they are generically disclosed and the final product using such intermediates has been explicitly enabled.

5. Claims 1-2, 11-19 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of U.S. Patent No. 6,465,453. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are fully embraced by the issued claim for n=2 compounds.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- 6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
  - A person shall be entitled to a patent unless -
  - (f) he did not himself invent the subject matter sought to be patented.

Claims 1-2, 11-19 are rejected under 35 U.S.C. 102(f) as being anticipated by Hertel US 6,436,964, WO 01/46142 or WO 01/46143.

Please note that Hertel US 6,436,964, WO 01/46142 or WO 01/46143 all have different inventive entities from the instant claims while it has been explained supra the although Hertel '964 did not explicitly exemplify the methyl or gem-dimethyl substituted compounds of the instant claims, such compounds are considered to be in possession by artisan since the final products employing such intermediates have been exemplified. The two WO patent "claimed"

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processes of making the methyl or gem-dimethyl substituted compounds of the instant claims, since such process of making the compounds is own and operated by "another", the product made by the processes of the two WO patent must be in possession by the "another". The two WO patent served as *evidence* that the issue of "who" is the first to invent of the instantly claimed compounds must be resolved.

Claims 1-2, 11-19 are directed to the same invention as that disclosed in the commonly assigned US 6,436,964 or WO 01/46142 or WO 01/46143. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.

Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Failure to comply with this requirement will result in a holding of abandonment of this application.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Celia Chang

Primary Examiner

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OACS/Chang May 15, 2003